

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

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Hand Delivered

March 20, 2000

Ms. Patricia Moe
Reregistration Branch (7508C)
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2, Room 625
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Malathion: Pathology Working Group Review of Liver Slides From the 24-Month Toxicity/Oncogenicity Study in the Rat (MRID 43942901)

Dear Ms. Moe:

On behalf of Cheminova A/S (Cheminova, EPA Company Number 4787), we are submitting three copies of the following documents:

- Pathology Working Group (PWG) Peer Review of Proliferative Lesions of the Liver in Female Rats in a 24 Month Oral Toxicity/Oncogenicity Study of Malathion; and
- Summary and Significance of the Results from the Pathology Working Group Peer Review of Proliferative Lesions of the Liver in Female Rats in a 24 Month Oral Toxicity/Oncogenicity Study of Malathion.

The Pathology Working Group review was conducted on March 15, 2000, according to PR Notice 94-5. The purpose of the PWG was to validate the accuracy and consistency of the initial histopathology examination for the diagnosis of proliferative lesions in the liver of female rats. The reviewing pathologist (Dr. Bill Busey) reexamined all sections of the liver from all animals in all control and treated groups for female rats. Following Dr. Busey's review, the PWG (a panel of expert pathologists) was convened to examine tissue sections (including all foci of cellular alteration, all hypertrophic/hyperplastic lesions, and hepatocellular

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neoplasms) from the liver from female rats diagnosed in the final study report and/or by the reviewing pathologist. The PWG provided a consensus diagnosis for each animal for which tissues were examined; validated treatment related effects, if any; and discussed their biological significance. The results of the PWG are provided in the enclosed report. The significance of the results are discussed in the enclosed summary document.

If you have any questions concerning the information in this letter, please do not hesitate to call me at (703) 312-8520.

Sincerely,



Diane Allemang
Jellinek, Schwartz & Connolly, Inc.
Authorized Representative for
Cheminova A/S

Enclosures

c: David Menotti, Shaw-Pittman
Don O'Shaughnessy, Cheminova, Inc.
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